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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/702,228

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Michael R. Slater

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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

10/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/702,228	Applicant(s) SLATER ET AL.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-27,36-48,67 and 75-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13-27,36-48 and 67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/8/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 13-27, 36-48, 67, 75-103 are pending in the case.

Claims 13-27, 36-48, 67 are withdrawn.

Receipt of Information Disclosure Statements on 10/14/09 and 12/12/08 is acknowledged.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection that were not necessitated by applicants' amendment and therefore, this action is final.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 83 (first occurrence) been renumbered 82.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 6,248,569) in view of Thach (US Patent 5,342,782), Kappelman et al. (Gene, 160, 1995, 55-98) (cited by applicant) and New England Biolab catalog.

Dunn et al. teach a vector comprising a site for a first restriction site that generates a 3'TA overhang (i.e. *PacI*) which is 5' to a site for a second restriction enzyme which generates blunt ends, (i.e. *HpaI*), and a promoter positioned 5' of the first site (See Fig. 2), such that DNA comprising an open reading frame inserted between the first and second site would have a 1 in three chance of being in frame with the open reading frame upstream of the first restriction site. (Dunn et al. also discloses a vector (Fig. 1A, 1B) comprising a first site for *PacI*, with sites for blunt cutters such as *ScaI* and *NruI* 3' of said site, with a promoter positioned 5' to the first site).

Thach teach that in order to obtain expression of an open reading frame of interest, it is placed in-frame downstream of a promoter in a vector teaches that one may adjust the sequence of an open reading frame such that it is in frame with a promoter upstream of the sequence, so that the correct reading frame is generated for the resultant protein (see col. 4, lines 36-65). It would have been obvious to one of ordinary skill in the art to have altered any out of frame sequence inserted in the vector of Dunn et al., in order to obtain the correct reading frame, as taught by Thach. The insertion of a sequence of interest into unique sites in a vector, using convenient sites, for expression of said sequence from a promoter on the vector, is a very well known

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method in the art, and such vectors are extremely well known and would have been obvious to one of ordinary skill in the art.

Kappelman et al. disclose the restriction enzyme Sgfl, which leaves 3'TA ends, and its 8 bp recognition site, and its usefulness for genome analysis (see abstract, see page 55).

New England Biolabs teaches recognition sites for restriction enzymes, including those used in the claimed vector, including PmeI, EcoRV, Ball, DraI, HincII, Scil, Swal, BsaBI, EcoICRI, Hyp81, MlyI, MslI, PshAI, SsspD51 or XmnI,. It would have been obvious to one of ordinary skill in the art to have altered any out of frame sequence inserted in the vector of Dunn et al., in order to obtain the correct reading frame, as taught by Thach. The insertion of a sequence of interest into unique sites in a vector, using convenient sites, for expression of said sequence from a promoter on the vector, is a very well known method in the art, and such vectors are extremely well known and would have been obvious to one of ordinary skill in the art. It also would have been obvious to one of ordinary skill in the art to have inserted a well known site such as Sgfl in the vector of Dunn et al. in view of Thach, since the use of any particular restriction enzyme site in a vector is well known in the art, and since the placement of known and useful restriction sites, such as Sgfl, in any vector, for manipulation of DNA, was extremely well known in the art. The placement of Sgfl in a vector would result in well known sequences when joined to a DNA of interest, and when treated with restriction enzymes whose recognition sites, and cleavage sites, were well known in the art. In the absence of evidence to the contrary, the placement of any restriction site, in any vector

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or DNA sequence, was obvious to one of ordinary skill in the art. Restriction enzymes, their recognition sites, the nucleotides overhangs that they leave, and the sequences that are formed when DNA treated with said enzymes is joined with a particular DNA of interest, were well known, as was the manipulation of DNA using known and useful restriction enzymes, including inserting sequences encoding any restriction site, at any region of any DNA molecule. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

The rejection is maintained essentially for the reasons made of record in the previous Office action, with slight modifications as necessitated by applicants amendment. Applicants arguments filed 12/9/08 have been considered but have not been found convincing. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While it is acknowledged that none of the references individually teach the claimed vectors, it is maintained that when considered in combination, the claimed invention would have been obvious to one of ordinary skill in the art. Applicant has argued that "none of the cited documents individually or in combination, provide a reasonable expectation of a vector capable to expressing and introduced open reading frame without or with a N-terminal fusion, where the vector has a site for a restriction enzyme that generates a 3'TA overhang, useful to form an

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exchange site at the 3' end of a vector backbone and 5' end of a DNA to be inserted.

The use of blunt ends forming an exchange site at the 5' end of a vector backbone and the 3' end of a DNA to be inserted allows for termination of a coding region in the DNA

insert near the exchange site. And the use of both 3' TA overhangs and blunt ends

allows for combinations of the above". This argument is not fully understood. In

addition, applicants argument that there was no reasonable expectation of the claimed vector, is not understood. The placement of restriction sites in convenient locations on

a vector had a very reasonable expectation of success, and is exactly predictable,

according to the well known behavior of restriction enzymes, and the manipulation of

DNA molecules using said restriction enzymes and recognition sites. There was no

reason not to expect that the placement of a well known enzyme recognition site, such

as Sgfl, upstream or 5' to a second restriction site which generates blunt ends, would

result in a vector with exactly predictable structure and function. Furthermore, the use

of restriction sites that leave particular overhangs, such as 3'TA, or which leave blunt

ends, and the subsequent ligation of appropriately matching DNA molecules with DNA

containing said sites and having been treated with restriction enzymes, was well known

in the art. There is no apparent significant advantage or unexpected result from the use

of any enzymes listed in the claims. Further, any vector having any restriction sites,

can be entirely synthesized in the laboratory, using well known techniques, and any

restriction site, can be placed at any location on any DNA molecule, using well known

techniques. Therefore there was nothing unexpected about the placement of an Sgfl

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sites, rare restriction sites, sites that generates blunt ends, sites that generate 3'TA overhangs, etc. on a vector for their known and useful properties.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
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